UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MARY SZARKOWSKI, Plaintiff, -against- TAKEDA PHARMACEUTICALS AMERICA, INC.; TAKEDA PHARMACEUTICALS U.S.A., INC., f/k/a TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.; TAKEDA PHARMACEUTICAL COMPANY LIMITED, ELI LILLY AND COMPANY, and ELI LILLY INDUSTRIES INC., Defendants.	:	**COMPLAINT** **JURY TRIAL DEMANDED**

COME NOW Plaintiff MARY SZARKOWSKI, by and through her attorneys, Napoli Shkolnik, PLLC, brings this complaint against Defendants TAKEDA PHARMACEUTICALS AMERICA, INC., TAKEDA PHARMACEUTICALS U.S.A., INC., f/k/a TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.; TAKEDA PHARMACEUTICAL COMPANY LIMITED, ELI LILLY AND COMPANY and ELI LILLY INDUSTRIES INC. as follows:

INTRODUCTION

1. This action involves claims of personal injury, economic damages, and other claims of damage arising from injuries sustained by Plaintiff, MARY SZARKOWSKI, as a direct and proximate result of both the defective nature of defendants TAKEDA PHARMACEUTICALS AMERICA, INC., TAKEDA PHARMACEUTICALS U.S.A., INC.,

f/k/a TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.; TAKEDA PHARMACEUTICAL COMPANY LIMITED, ELI LILLY AND COMPANY and ELI LILLY INDUSTRIES INC. pharmaceutical product, Actos. Actos® (generic name pioglitazone), is a prescription medication used to improve blood sugar (glucose) control in adults with Type II diabetes. Actos, at all times relevant hereto, was manufactured designed, tested, packaged, labeled, marketed, advertised, distributed, prescribed, and sold by Defendants identified herein.

PARTIES AND JURISDICTION

2. At all times relevant hereto, Plaintiff MARY SZARKOWSKI was and is a resident of Massachusetts.

3. Takeda Pharmaceuticals America, Inc. ("Takeda America") is a Delaware Corporation, which has its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

4. Takeda America is a wholly owned subsidiary of Takeda U.S.A.

5. Takeda Pharmaceuticals U.S.A., Inc. f/k/a Takeda North America, Inc.("Takeda U.S.A.") is a Delaware corporation, which has its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

6. Takeda U.S.A. is a wholly owned subsidiary of Takeda Limited.

7. Takeda Pharmaceutical Company Limited ("Takeda Limited") is a foreign corporation with its principal place of business located at 1-1, Doshomachi 4-chrome, Chuo-ku, Osaka, 540-8645, Japan.

8. Takeda Limited is the parent company of Takeda U.S.A., and Takeda America is a wholly owned subsidiary of Takeda U.S.A.

9. Takeda Limited and Takeda U.S.A. have derived substantial revenue from goods and products disseminated and used in the State of Massachusetts, including the Actos product prescribed to and used by Plaintiff in the State of Massachusetts.

10. Eli Lilly and Company ("Lilly") is an Indiana corporation with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285.

11. Eli Lilly Industries Inc. ("Lilly Industries") is a Delaware corporation with its principal place of business located at 65 De Inf Km 12 6 Ave., Carolina, PR 00979. Lilly Industries is a wholly owned subsidiary of Eli Lilly and Company.

12. Lilly and Lilly Industries have derived substantial revenue from goods and products disseminated and used in the State of Massachusetts, including the Actos product prescribed to and used by Plaintiff in the State of Massachusetts.

13. This Court has personal jurisdiction over the Defendants based on Diversity of Citizenship pursuant to 28 U.S.C. Section 1332(a)(1), and the amount in controversy is well in excess of the jurisdictional limit of $75,000.

FACTUAL BACKGROUND

14. Defendants, directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted and sold Actos™, for the treatment of Type II diabetes mellitus.

15. According to the American Diabetes Association, Type II diabetes is the most common form of diabetes. Type II diabetes develops when the body does not produce enough insulin or does not efficiently use the insulin that it does produce. Type I diabetes occurs when the body does not produce any insulin at all. Insulin is necessary for the body to be able to use glucose for energy.

14. Actos® was approved by the Food and Drug Administration ("FDA") in July of 1999 to treat Type II diabetes.

15. Actos was jointly launched by Takeda North America and Lilly in 1999.

16. Actos® is in a class of insulin-sensitizing diabetes agents known as thiazolidinediones ("TZDs").

17. Once Actos was approved by the FDA, Takeda and Lilly began to aggressively market Actos in the United States.

18. The approval of Actos occurred shortly after a competing OAD TZD, Avandia, was approved. Avandia was researched and developed by GlaxoSmithKline, Inc. and is in the same class of OADs as Actos in that it increases insulin sensitivity through PPAR gamma activation. From the moment Actos entered the market, the two products battled head-to-head in the marketplace and this competition made the concealment of any bladder cancer risk all the more important.

19. Once Actos was on the market, Takeda and Lilly competed against Avandia by asserting that, unlike Avandia, Actos lowered bad cholesterol (LDLs) and raised good cholesterol (HDLs). Takeda and Lilly made this claim because Actos was shown, in addition to activating PPAR gamma, to also activate PPAR alpha. PPAR alpha is a sister protein to PPAR gamma, which regulates and affects how a cell engages in its metabolic process, i.e., how the cell uses energy. PPAR alpha typically presents or "activates" under conditions of energy deprivation. Takeda and Lilly had concluded that, in addition to being a PPAR gamma agonist (i.e., activator), Actos was also a PPAR alpha agonist, giving it similar qualities to fibrate (cholesterol lowering) medications. And, since PPAR alpha activation is associated with improving cholesterol profiles, Takeda and Lilly used this fact to claim that Actos provided, in

addition to improving insulin sensitivity, improved cholesterol benefits. Avandia, however, did not have comparable PPAR alpha activation. Thus, since Type 2 diabetes is associated with obesity, the reduction of cholesterol risks in addition to controlling blood sugar operated as an "important hook" in convincing physicians of Actos' superiority over Avandia. Indeed, in sales representative training materials, Takeda and Lilly representatives were specifically instructed to promote Actos as superior to Avandia because Actos "has a small degree of PPAR [alpha] affinity and activity, while Avandia has been reported to have none."

20. In line with this marketing approach, on October 27, 2000, several scientists for Takeda published *Activation of Human Peroxisome Proliferator-Activated Receptor (PPAR) Subtypes by Pioglitazone* in the Biochemical and Biophysical Research Communications medical journal. In this article, the Takeda scientists stated that Actos, in addition to being a PPAR gamma agonist, was also a weak PPAR alpha agonist, and that the scientists observed that Actos caused PPAR alpha activation.

21. On April 20, 2006, Takeda Limited announced the conclusion of its collaboration in the United States between Takeda North America and Lilly to promote and market Actos.

22. Takeda Limited described this partnership as "a great success" and "mutually beneficial to both companies."

23. Actos® exerts its antihyperglycemic effect only in the presence of endogenous insulin. Therefore, Actos® is only used to treat Type II diabetes and should not be used to treat Type I diabetes.

24. Actos® is also sold in combination with metformin (Actoplus Met, Actoplus Met XR) and in combination with glimepiride (Duetact).

25. As a result of the defective nature of Actos®, persons who were prescribed and ingested Actos® for more than twelve months, including Plaintiff, were at increased risk for developing bladder cancer, have suffered and may continue to suffer from bladder cancer.

26. As a result of the defective nature of Actos®, persons who were prescribed and ingested Actos® for more than twelve months, including Plaintiff, developed bladder cancer, have suffered and may continue to suffer from bladder cancer.

27. Defendants concealed their knowledge that Actos® can cause bladder cancer from Plaintiff, other consumers, and the medical community.

28. Specifically, Defendants did not adequately inform consumers and the prescribing medical community about the risks of bladder cancer with use of Actos® for more than twelve months.

29. As a result of Defendants' actions and inactions, Plaintiff was injured due to ingestion of Actos®, which caused and will continue to cause Plaintiff various injuries and damages. Plaintiff accordingly seeks damages associated with these injuries.

30. Prior to Actos® being approved by the FDA, a two-year carcinogenicity study was conducted on male and female rats. Drug-induced tumors were observed in male rats receiving doses of Actos® that produced blood drug levels equivalent to those resulting from a clinical dose.

31. In 2005, the results of the PROactive (PROspective PioglitAzone Clinical Trial In MacroVascular Events) three-year study were published. PROactive prospectively looked at the impact in total mortality and macrovascular morbidity using Actos®. Dormandy J.A., et al. Secondary Prevention of Macrovascular Events in Patients with Type II Diabetes in the

PROactive Study (PROspective PioglitAzone Clinical Trial In MacroVascular Events): a Randomised Controlled Trial, Lancet, 266:1279-1286 (2005) (the "Dormandy paper").

32. The PROactive study was looking at cardiovascular events and outcomes.

33. During the course of monitoring the study, the researchers and Defendants became aware that there was a statistically significant demonstrated higher percentage of bladder cancer cases in patients receiving Actos® versus comparators.

34. Neither during the study, nor in the actual final Dormandy paper, did the researchers or the Defendants publish these statistically significant increases of bladder cancer.

35. This information was not included in the published Dormandy paper.

36. Defendants willfully, wantonly and with malice withheld the knowledge of increased risk of cancer in users of Actos® to prevent any chance of its products' registrations being delayed or rejected by FDA.

37. A three-year liver safety study was also performed, and according to the FDA, that study also demonstrated a higher percentage of bladder cancer cases in patients receiving Actos® versus comparators.

38. On September 17, 2010, the FDA issued a Safety Announcement stating it was undertaking a review of the data from an ongoing, ten-year epidemiological study being conducted by Kaiser Permanente to evaluate the association between Actos® and bladder cancer. The planned five-year interim analysis demonstrated that the risk of bladder cancer increases with increasing dose and duration of Actos® use, reaching statistical significance after 24 months.

39. Despite FDA finding that Actos® is linked to a statistically significant increase in the risk for developing bladder cancer, Robert Spanheimer, Vice President of Medical and

Scientific Affairs for Takeda, claimed to Reuters that the Kaiser Permanente study has not shown a risk to patients of bladder cancer or other cancers from Actos®.

40. In early 2011, the American Diabetes Association published Piccinni, et al. *Assessing the Association of Pioglitazone Use and Bladder Cancer Through Drug Adverse Event Reporting*, *Diabetes Care*, 34:1369-1371 (June 2011), published ahead of print April 22, 2011. This study looked at adverse events reports made to the FDA between 2004 and 2009. The conclusion of that study was that "[i]n agreement with preclinical and clinical studies, AERS analysis is consistent with an association between pioglitazone and bladder cancer. This issue needs constant epidemiologic surveillance and urgent definition by more specific studies."

41. On June 9, 2011, the European Medicines Agency announced that it had been informed by the French Medicines Agency of its decision to suspend the use of pioglitazone containing medicines (Actos®, Competact) in France while awaiting the outcome of the ongoing European review.

42. France's decision was based upon a retrospective cohort study in France using the French National Health Insurance Plan, which demonstrated a statistically significant increase in the risk for bladder cancer in males exposed to Actos® for more than a year. The French cohort included 1.5 million patients with diabetes that were followed for 4 years (2006-2009).

43. On June 10, 2011, Reuters published that Germany had joined France in suspending the use of Actos® after Germany's Federal Institute for Drugs and Medical Devices. ("BfArM") reviewed the results of the French study. BfArM recommended that doctors should not put new patients on pioglitazone.

44. On June 15, 2011, the FDA issued another Safety Announcement stating that "use of the diabetes medication Actos® (pioglitazone) for more than one year may be associated with

an increased risk of bladder cancer." The FDA ordered information about this risk to be added to the Warnings and Precautions section of the label for pioglitazone-containing medicines.

45. The FDA reported that the risk of bladder cancer increased with increasing dose and duration of pioglitazone use. When compared to persons never exposed to pioglitazone, exposure to pioglitazone therapy for longer than 12 months was associated with a 40% increase in risk. Based on this data, the FDA calculated that therapy with Actos® for longer than 12 months was associated with 27.5 excess cases of bladder cancer per 100,000 person-years follow-up, compared to those who never used pioglitazone.

46. On July 12, 2011, Takeda Limited issued a recall on Actos® in France.

47. Following the recall in France, Takeda Limited refused to issue a recall of Actos® in the United States thereby continuing to subject American citizens to the significant risk of developing bladder cancer while ensuring the users in France and Germany were no longer subject to this risk.

48. As the manufacturers and distributors of Actos®, Defendants knew or should have known that Actos® use for longer than twelve months was associated with bladder cancer.

49. With the knowledge of the true relationship between long-term use of Actos® and developing bladder cancer, rather than take steps to pull the drug off the market, Defendants promoted Actos® as a safe and effective treatment for Type II diabetes.

50. Piccinni, et al. analyzed the association between antidiabetic drugs and bladder cancer by reviewing reports from the FDA Adverse Event Reporting System between 2004 and 2009. The association was analyzed by the case/noncase methodology. There were 31 recorded reports of bladder cancer in patients using pioglitazone. Piccinni's results indicated that the reporting odds ratio for pioglitazone was indicative of a "definite risk." Piccinni, et al. *Assessing*

the Association of Pioglitazone Use and Bladder Cancer Through Drug Adverse Event Reporting, *Diabetes Care*, 34:1369-1371 (June 2011), published ahead of print April 22, 2011.

51. Despite their knowledge of this dangerous side effect that can result from Actos® use, Defendants refused to warn patients, physicians and the medical community about the risk of bladder cancer.

52. Actos® is one of Defendants' top selling drugs. Upon information and belief, in the last year, the medication had global sales of $4.8 billion and accounted for approximately 27% of Takeda's revenue.

53. In 2008, with the knowledge of the risk associated with developing bladder cancer while using Actos® long term, Takeda Limited achieved its marketing goal by making Actos® the tenth best-selling medication in the United States all while placing American citizens at risk of developing bladder cancer.

54. On December 12, 2016, the FDA tendered a safety announcement, indicating that "use of the type 2 diabetes medicine pioglitazone (Actos, Actoplus Met, Actoplus Met XR, Duetact, Oseni) may be linked to an increased risk of bladder cancer." In particular, it was noted that "**[h]ealth care professionals** should not use pioglitazone in patients with active bladder cancer, and should carefully consider the benefits and risks before using pioglitazone in patients with a history of bladder cancer." (emphasis in original). Ultimately, the FDA concluded that "[o]verall, the data suggest that pioglitazone use may be linked to an increased risk of bladder cancer."

55. Consumers, including Plaintiff, who have used Actos® for treatment of Type II diabetes, have several alternative safer products available to treat the conditions and have not

been adequately warned about the significant risks and lack of benefits associated with long-term Actos® therapy.

56. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and her physicians the true and significant risks associated with long-term Actos® use.

57. As a result of Defendants' actions, Plaintiff and her physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of Defendants' conduct.

NATURE OF THE CASE

58. In or around 2010, Plaintiff was prescribed and began taking Actos® upon direction of her physician for long-term maintenance of Type II diabetes. Subsequently, as a direct result of ingestion of Actos®, Plaintiff was diagnosed with bladder cancer in or around October 2014.

59. As a direct result of being prescribed Actos® for many years, Plaintiff has been permanently and severely injured, having suffered serious consequences from long-term Actos® use.

60. Plaintiff requires and will in the future require ongoing medical care and treatment.

61. Plaintiff, as a direct and proximate result of long-term Actos® use, suffered severe mental and physical pain and suffering and has and will sustain permanent injuries and emotional distress, along with economic loss due to medical expenses, and living-related expenses due to her new lifestyle.

62. Plaintiff would not have used Actos® had Defendants properly disclosed the risks associated with its long-term use.

FIRST CAUSE OF ACTION
AS AGAINST ALL DEFENDANTS
(STRICT LIABILITY)

63. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

64. At all times relevant hereto, the Defendants manufactured, designed, distributed, and/or sold Actos®.

65. At all times relevant hereto, the dangerous propensities of Actos® were known to Defendants, or reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold their respective products, and not known to ordinary physicians who would be expected to prescribe the drug for their patients.

66. The Actos® products as distributed by Defendants were defective and unreasonably dangerous prescription drug products, as Defendant failed to provide appropriate and adequate warnings and instructions to render the products reasonably safe for their ordinary, intended, and reasonably foreseeable uses; in particular—the common, foreseeable and intended use of Actos® therapy as long-term maintenance for Type II diabetes.

67. As a direct, foreseeable and proximate result of Defendants' defective Actos® product, Plaintiff suffered grievous bodily injuries and consequent economic and other losses, as referenced above, when her physicians, lacking adequate warnings and other appropriate facts that were misrepresented or omitted from the information (if any) Defendants provided to

physicians for their respective products, prescribed for Plaintiff the use of Actos® for a prolonged and unwarranted period of time. Plaintiff has suffered and will continue to suffer injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income and disability.

SECOND CAUSE OF ACTION
AS AGAINST ALL DEFENDANTS
(NEGLIGENCE)

68. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

69. At all times relevant hereto, it was the duty of the Defendants to use reasonable care in the manufacturing, design, distribution, and/or sale of the aforesaid Actos®.

70. In disregard of its aforesaid duty, the Defendants were guilty of one or more of the following negligent acts or omissions:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and distributing Actos® without thorough and adequate pre and post-market testing of the product;

b. Manufacturing, producing, promoting, advertising, formulating, creating, developing, and designing, and distributing Actos® while negligently and intentionally concealing and failing to disclose clinical data which demonstrated the risk of serious harm associated with the use of Actos®;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Actos® was safe for its intended use;

d. Failing to disclose and warn of the product defect to the regulatory agencies, the medical community, and consumers that Defendants knew and had reason to know that Actos® was indeed unreasonably unsafe and unfit for use by reason of the product's defect and risk of harm to its users in the form of, but not limited to, the development of bladder cancer;

e. Failing to warn Plaintiff, the medical and healthcare community, and

consumers that the product's risk of harm was unreasonable and that there were safer and effective alternative Type II diabetic medications available to Plaintiff and other consumers;

f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would prescribe, use, and consume Actos®;

g. Advertising, marketing, and recommending the use of Actos®, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with, and inherent in, the use of Actos®;

h. Representing that Actos® was safe for its intended use when in fact Defendants knew and should have known the product was not safe for its intended purpose;

i. Failing to disclose to and inform the medical community and consumers that other forms of safer and effective alternative Type II diabetic medications were available for use for the purpose for which Actos® was manufactured;

j. Continuing to manufacture and sell Actos® with the knowledge that Actos® was unreasonably unsafe and dangerous;

k. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Actos® so as to avoid the risk of serious harm associated with the use of Actos®;

l. Failing to design and manufacture Actos® so as to ensure the drug was at least as safe and effective as other Type II diabetic medications;

m. Failing to ensure the product was accompanied by proper and accurate warnings about possible adverse side effects associated with the use of Actos® and that use of Actos® created a high risk of developing bladder cancer;

n. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of Actos®.

71. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff MARY SZARKOWSKI has developed and been diagnosed with bladder cancer.

Plaintiff has suffered and will continue to suffer injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and disability.

THIRD CAUSE OF ACTION
AS AGAINST ALL DEFENDANTS
STRICT LIABILITY – FAILURE TO WARN

72. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

73. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, marketed, and/or introduced Actos into the stream of commerce, and in the course of the same, directly advertised or marketed Actos and pioglitazone hydrochloride to consumers or persons responsible for consumers, and therefore, had a duty to both Plaintiff and Plaintiff's physician(s) to warn of risks associated with the use of the product.

74. Defendants had a duty to warn of adverse drug reactions, which they know or have reason to know can be caused by the use of Actos and pioglitazone hydrochloride and/or are associated with the use of Actos and pioglitazone hydrochloride.

75. The Actos and pioglitazone hydrochloride manufactured and/or supplied by the Defendants was defective due to inadequate post-marketing warnings and/or instructions because, after the Defendants knew or should have known of the risks of bladder cancer from Actos use, they failed to provide adequate warnings to consumers of the product, including Plaintiff and Plaintiff's physician(s), and continued to aggressively promote Actos.

76. Due to the inadequate warning regarding bladder cancer, Actos was in a defective condition and unreasonably dangerous at the time that it left the control of the Defendants.

77. Defendants failed to adequately warn Plaintiff and Plaintiff's physician(s) of human and animal results in preclinical studies pertaining to bladder cancer and Actos.

78. Had Plaintiff been adequately warned of the potential life-threatening side effects of the Defendants' Actos and pioglitazone hydrochloride, Plaintiff would not have purchased or taken Actos and could have chosen to request other treatments or prescription medications.

79. Upon information and belief, had Plaintiff prescribing physician(s) been adequately warned of potential life-threatening side effects of the Defendants' Actos and pioglitazone hydrochloride, Plaintiff prescribing physician(s) would have discussed the risks of bladder cancer and Actos with Plaintiff and/or would not have prescribed it.

80. As a foreseeable and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff was caused to suffer from the aforementioned injuries and damages.

81. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff MARY SZARKOWSKI has developed and been diagnosed with bladder cancer. Plaintiff has suffered and will continue to suffer injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and disability.

FOURTH CAUSE OF ACTION
AS AGAINST ALL DEFENDANTS
STRICT LIABILITY – DESIGN DEFECT

82. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

83. Actos was expected to, and did, reach the intended consumers, handlers, and persons coming into contact with the product without substantial change in the condition in which it was produced, manufactured, sold, distributed, labeled, and marketed by Defendants.

84. At all times relevant, Actos was manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition, which was dangerous for use by the public, and, in particular, by Plaintiff.

85. Actos and pioglitazone hydrochloride as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed by Defendants was defective in design and formulation in that when it left the hands of the Defendants' manufacturers and/or suppliers the foreseeable risks exceeded the alleged benefits associated with the design and formulation of Actions.

86. Actos and pioglitazone hydrochloride as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed by Defendants was defective in design and formulation in that when it left the hands of the Defendants' manufacturers and/or suppliers it was unreasonably dangerous and was also more dangerous than the ordinary customer would expect.

87. At all times herein mentioned, Actos and pioglitazone hydrochloride was in a defective condition and was unsafe, and Defendants knew and had reason to know that the product was defective and inherently unsafe, especially when Actos was used in a form and manner instructed and provided by the Defendants.

88. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, common, intended use.

89. At the time of Plaintiff's use of Actos, it was being used for its intended purpose, and in a manner normally intended, namely for the treatment of Type 2 Diabetes Mellitus.

90. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, marketed, and/or introduced a defective product that caused an unreasonable risk to the health of consumers, and to Plaintiff in particular, and Defendants are therefore strictly liable for the injuries and damages sustained by Plaintiff.

91. At the time Defendants' product left their control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Actos. This was demonstrated by the existence of other Type 2 Diabetes Mellitus medications which had a more established safety profile and a considerably lower risk profile.

92. Plaintiff could not, in the reasonable exercise of care, have discovered Actos' defects and perceived its danger.

93. The defects in Defendants' product were substantial and contributing factors in causing Plaintiff's injuries. As a foreseeable, direct, and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff was caused to suffer from the aforementioned injuries and damages.

94. Due to the unreasonably dangerous condition of Actos, Defendants are strictly liable to Plaintiff.

95. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff MARY SZARKOWSKI has developed and been diagnosed with bladder cancer. Plaintiff has suffered and will continue to suffer injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and disability.

FIFTH CAUSE OF ACTION
AS AGAINST ALL DEFENDANTS
(BREACH OF EXPRESS WARRANTY)

96. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

97. Defendants expressly warranted that Actos® was safe and well accepted by users.

98. Actos® does not conform to these express representations because Actos® is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendants.

99. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and will continue to suffer severe and permanent personal injuries, harm and economic loss.

100. Plaintiff did rely on the express warranties of the Defendants herein.

101. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of Actos® in recommending, prescribing and dispensing Actos.

102. The Defendants herein breached the aforesaid express warranties, as their drug Actos was defective.

103. Defendants expressly represented to Plaintiff, Plaintiff's physicians, healthcare providers, and the FDA that Actos® was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for reducing and controlling the blood sugar of patients with type II diabetes.

104. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Actos® was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

105. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including bladder cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished

enjoyment of life, shortened life expectancy, expenses for hospitalization, loss of earnings and other economic and non-economic damages.

106. By reason of the foregoing, Plaintiffs have suffered injuries and damages as alleged herein.

SIXTH CAUSE OF ACTION
AS AGAINST ALL DEFENDANTS
(BREACH OF IMPLIED WARRANTIES)

107. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

108. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Actos® to reduce and control blood sugar in type II diabetic patients.

109. At the time Defendants marketed, sold and distributed Actos® for use by Plaintiff, Defendants knew of the use for which Actos® was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

110. The Defendants impliedly represented and warranted to the users of Actos® and their physicians, healthcare providers, and the FDA that Actos was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

111. That said representations and warranties aforementioned were false, misleading and inaccurate in that Actos was unsafe, unreasonably dangerous, improper, not of merchantable quality and defective.

112. Plaintiff and members of the medical community and healthcare professions did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

113. Plaintiff and Plaintiff's physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether Actos was of merchantable quality and safe and fit for its intended use.

114. Actos was placed into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

115. The Defendants herein breached the aforesaid implied warranties, as their drug Actos® was not fit for its intended purposes and uses.

116. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization, loss of earnings and other economic and non-economic damages.

WHEREFORE, Plaintiffs demands judgment against each of the Defendants jointly and severally for such sums, including, but not limited to prejudgment and post-judgment interest, as would be necessary to compensate the Plaintiffs for the injuries Plaintiffs have and will suffer. Plaintiffs further demand judgment against each of the Defendants for punitive damages. Plaintiffs further demand payment by each of the Defendants jointly and severally of the costs and attorney fees of this action. Plaintiffs further demand payment by each Defendant jointly and severally of interest on the above and such other relief as the Court deems just.

Dated: September 14, 2017

MARY SZARKOWSKI,

By her attorneys:

By: /s/ Nicholas B. Carter

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